FEWER INTERVENTIONS FOR AV FISTULA PATIENTS

The IN.PACT AV Access Clinical Trial

TRIAL OVERVIEW

A prospective, global, multicenter, single-blinded, randomized (1:1) clinical study of IN.PACT™ AV DCB vs Standard PTA with 330 patients.

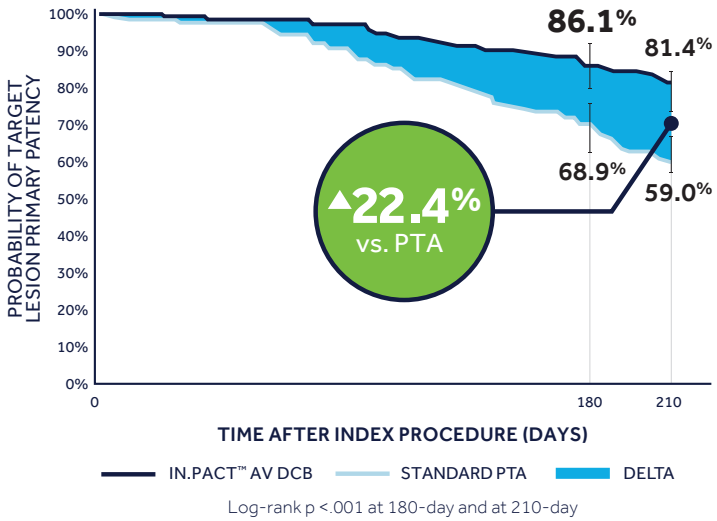
BASELINE CHARACTERISTICS

	IN.PACT™ AV DCB (N=170 Subjects)	Standard PTA (N=160 Subjects)	p-value[1]
Age, yrs (Mean ± SD)	65.8 ± 13.1	65.5 ± 13.4	0.837
Male Gender	65.9%	63.1%	0.646
AVF Type			0.918
Radiocephalic	50.6%	50.0%	
Brachiocephalic	36.5%	36.3%	
Brachiobasilic	10.0%	9.4%	
Other	2.9%	4.4%	
Years since AVF Creation			
Mean ± SD	3.2 ± 3.0	3.5 ± 3.8	0.436
Years of HD History			
Mean ± SD	4.3 ± 5.1	4.2 ± 5.2	0.755

LESION CHARACTERISTICS

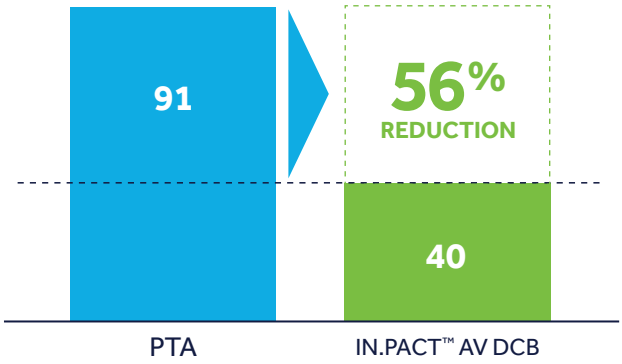
	IN.PACT™ AV DCB (N=170 Subjects)	Standard PTA (N=160 Subjects)	p-value[1]
Target Arm			0.449
Right Arm	23.5%	27.5%	
Left Arm	76.5%	72.5%	
Dominant Arm	22.4%	24.4%	0.697
Lesion Type			0.905
De Novo	30.0%	30.6%	
Restenotic	70.0%	69.4%	
Total Lesion Length (mm)	46.9 ± 28.1	40.0 ± 25.7	0.021

HIGHEST REPORTED PRIMARY PATENCY IN AN AV DCB STUDY[2]



Log-rank p <.001 at 180-day and at 210-day

Number of reinterventions required to maintain target lesion primary patency[2]



The largest global, randomized, AV fistula drug-coated balloon study conducted, with subjects from Japan, New Zealand, and the United States.

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Ordering Information

Ref. Number Usable Length 40 cm	Ref. Number Usable Length 80 cm	Ref. Number Usable Length 130cm	Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (F)	Nominal Pressure (atm)	RBP (atm)
IAV04004004P	IAV04004008P	-	4	40	5	8	14
IAV04006004P	IAV04006008P	-	4	60	5	8	14
IAV04008004P	IAV04008008P	-	4	80	5	8	14
IAV04012004P	IAV04012008P	-	4	120	5	8	14
IAV05004004P	IAV05004008P	-	5	40	6	8	14
IAV05006004P	IAV05006008P	-	5	60	6	8	14
IAV05008004P	IAV05008008P	-	5	80	6	8	14
IAV05012004P	IAV05012008P	-	5	120	6	8	14
IAV06004004P	IAV06004008P	-	6	40	6	8	14
IAV06006004P	IAV06006008P	-	6	60	6	8	14
IAV06008004P	IAV06008008P	-	6	80	6	8	14
IAV06012004P	IAV06012008P	-	6	120	6	8	14
IAV07004004P	IAV07004008P	-	7	40	7	8	14
IAV07006004P	IAV07006008P	-	7	60	7	8	14
IAV07008004P	IAV07008008P	-	7	80	7	8	14
IAV08004004P	IAV08004008P	IAV08004013P	8	40	7	8	10
IAV08006004P	IAV08006008P	IAV08006013P	8	60	7	8	10
IAV08008004P	IAV08008008P	IAV08008013P	8	80	7	8	10
IAV09004004P	IAV09004008P	IAV09004013P	9	40	7	8	10
IAV09006004P	IAV09006008P	IAV09006013P	9	60	7	8	10
IAV09008004P	IAV09008008P	IAV09008013P	9	80	7	8	10
IAV10004004P	IAV10004008P	IAV10004013P	10	40	7	6	9
IAV12004004P	IAV12004008P	IAV12004013P	12	40	9	6	9

REFERENCES

1. p-values for continuous variables were based on independent t-test, for binary variables were based on Fisher's Exact test, for nominal variables were based on CMH general association test, for ordinal variables were base on CMH score test.

2. Results from the IN.PACT™ AV Access Clinical Trial found in the IN.PACT™ AV drug-coated balloon (DCB) Instructions For Use (IFU).

Target Lesion Primary Patency Rate: Defined as freedom from clinically driven target lesion revascularization (CD-TLR) or access circuit thrombosis.

Reduction in reinterventions: Defined as the number of interventions required to maintain target lesion primary patency calculated at 210 days.

INDICATIONS FOR USE

The IN.PACT™ AV Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, for the treatment of obstructive lesions up to 100 mm in length in the native arteriovenous dialysis fistulae with reference vessel diameters of 4 to 12 mm.

CONTRAINDICATIONS

The IN.PACT AV DCB is contraindicated for use in the following anatomy and patient types:

- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant, or are intending to become pregnant, or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure

WARNINGS

- **A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Inadequate information is available to evaluate the potential mortality risk associated with the use of paclitaxel-coated devices for the treatment of other diseases/conditions, including this device indicated for use in arteriovenous dialysis fistulae. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options for their specific disease/condition with their patients.**
- Use the product prior to the Use-by date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT AV DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety of using multiple IN.PACT AV DCBs with a total drug dosage exceeding 15,105 µg paclitaxel has not been evaluated clinically.

PRECAUTIONS

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents. Identify allergic reactions to contrast media and antiplatelet therapy before treatment and consider alternatives for appropriate management prior to the procedure.
- This product is not intended for the expansion or delivery of a stent.
- Do not use the IN.PACT AV DCB for pre-dilatation or for post-dilatation.
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events
- The safety and effectiveness of the IN.PACT AV DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- Appropriate vessel preparation, as determined by the physician to achieve residual stenosis of ≤ 30%, is required prior to use of the IN.PACT AV DCB. Vessel preparation of the target lesion using high-pressure PTA for pre-dilatation was studied in the IN.PACT AV Access clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT AV DCB.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects which may be associated with balloon catheterization may include, but are not limited to, the following: abrupt vessel closure, allergic reaction, arrhythmias, arterial or venous aneurysm, arterial or venous thrombosis, death, dissection, embolization, hematoma, hemorrhage, hypotension/hypertension, infection, ischemia or infarction of tissue/organ, loss of permanent access, pain, perforation or rupture of the artery or vein, pseudoaneurysm, restenosis of the dilated vessel, shock, stroke, vessel spasms or recoil.

Potential complications of peripheral balloon catheterization include, but are not limited to, the following: balloon rupture, detachment of a component of the balloon and/or catheter system, failure of the balloon to perform as intended, failure to cross the lesion. These complications may result in adverse effects.

Although systemic effects are not anticipated, potential adverse effects not captured above that may be unique to the paclitaxel drug coating include, but are not limited to, the following: allergic/immunologic reaction, alopecia, anemia, gastrointestinal symptoms, hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia), hepatic enzyme changes, histologic changes in vessel wall, including inflammation, cellular damage, or necrosis, myalgia/arthralgia, myelosuppression, peripheral neuropathy.

Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.

Please reference appropriate product Instructions for Use for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

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